DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Changzhou Dingjian Medical Appliance Company, Limited
% Mr. Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Company, Limited
7th Floor, Jingui Business Building, 982 Congyun Road
Baiyun District, Guangzhou, Guangdong, 510420
CHINA

December 11, 2015

Re: K143013
Trade/Device Name: Spinal Inner Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: November 16, 2015
Received: November 24, 2015

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143013

Device Name
Spinal Inner Fixation System

Indications for Use *(Describe)*

Spinal inner fixation system is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Changzhou Dingjian Medical Appliance Co., Ltd.

No. 19 Juxiang Road

Wujin Economic Development Zone

Changzhou, Jiangsu Province, 213149, China

Primary Contact Person: Mike Gu

Regulatory Affairs Manager

OSMUNDA Medical Device Consulting Co., Ltd

Tel: (+86) 20-6232 1333

Fax: (+86) 20-8633 0253

Secondary Contact Person: Li Qingsong

Changzhou Dingjian Medical Appliance Co., Ltd.

Tel: 0086-13584330156

Fax: 0086-519-89603573

Date Prepared: October 05, 2014

II. DEVICE

Name of Device:	Spinal Inner Fixation System
Common/Usual Name:	Pedicle screw spinal system
Classification Names:	21 CFR 888.3070 Pedicle screw spinal system, 21 CFR 888.3050 Spinal interlaminal fixation orthosis
Regulation Class:	II
Product Code:	MNH, KWP, MNI

III. PREDICATE DEVICE

Primary predicate: General Spinal System K122994;

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Spinal inner fixation system consists of a variety of shapes and sizes of pedicle screws, rods, hooks, transverse linking pole assembly, and connecting components (side, domino, and axial), which can be rigidly locked into a variety of configurations. These components are made of titanium alloy per ASTM F136.

V. INDICATIONS FOR USE

Spinal inner fixation system is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Spinal inner fixation system employs the same technology as its predicate device K122994. Both have the same indication for use and are made of same raw materials; the bench tests were conducted to verify that the proposed device met all design specifications as was substantially equivalent to the predicate device.

Specification	Predicate Device General Spinal System K122994	Proposed Device Spinal inner fixation system

Manufacturer	Weigao Orthopaedic Device Co., Ltd.	Changzhou Dingjian Medical Appliance Co., Ltd.
Class	II	
Product Code	MNH, KWP, MNI	
Regulation Number	21 CFR 888.3070, 21 CFR 888.3050	
Intended Use	Intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft. The levels of fixation are T8 – S1.	
Indications for Use	The levels of fixation are T8 – S1	
Patient Population	The device is to be used in skeletally mature patients	
Prescription/OTC Use	Prescription use	
Static compression bending: yield load	Similar, the testing results show no statistically significant difference between two samples groups	
Static compression bending: stiffness	Similar, the testing results show no statistically significant difference between two samples groups	
Dynamic compression bending	Similar, the testing results show no statistically significant difference between two samples groups	
Static torsion: yield torque	Similar, the testing results show no statistically significant difference between two samples groups	
Static torsion: torsional stiffness	Similar, the testing results show no statistically significant difference between two samples groups	
Materials	Titanium alloy (TiAl4V ELI) which conforms to ASTM F136	Titanium alloy (TiAl4V ELI) which conforms to ASTM F136

Biocompatibility	Titanium alloy (TiAl4V ELI) which conforms to ASTM F136	Titanium alloy (TiAl4V ELI) which conforms to ASTM F136
Sterility	Provided as non-sterile, needs autoclave prior to use	Provided as non-sterile, needs steam sterilization prior to use

The following technological differences exist between the subject and predicate device:

- Size of components should be chosen based on patient's body size. The size difference between the proposed device and its predicate does not affect their clinical performance.
- The testing results of the static compression bending test, dynamic compression bending test and static torsion test are similar ,however no statistically significant difference between two samples groups

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Mechanical testing

According to the ASTM F1717, the following tests were carried out:

- Static compression bending test
- Dynamic compression bending test
- Static torsion test

Dissociation testing of screw head

Biocompatibility testing:

The Spinal inner fixation system has permanent contact (>30 days) with bone and tissue.

The Spinal inner fixation system is made of Ti-6Al-4V. According to the ASTM F136, the

materials have been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.

There is no Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in this Orthopedic Device.

Animal and clinical study

The subject of this premarket submission, Spinal inner fixation system, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data supports the substantial equivalence of the device and the performance testing report demonstrates that the Spinal inner fixation system should perform as intended in the specified use conditions. Changzhou Dingjian Medical Appliance Co., Ltd., Inc considers the Spinal inner fixation system does not raise any new issues of safety or effectiveness.